

REMARKS

Courtesies extended to Applicants' representative during the personal interview held on November 13, 2008, are acknowledged with appreciation. The substance of that interview is as described herein and in the Interview Summary dated November 13, 2008.

As discussed at the personal interview, the present invention provides methods for treatment of FXR-mediated diseases employing novel compounds having the defined structures set forth in the claims. In a particular aspect, the present invention relates to methods for treatment of hypercholesterolemia or cholestasis employing the novel compounds described herein.

By the present communication, claims 1, 2 and 3 have been amended to define Applicants' invention with greater particularity. No new matter is introduced by the subject amendments as the amended claim language is fully supported by the specification and original claims. For example, support for amended claim 1 can be found at claims 36 and 37. In view of the amendments to claim 1 submitted herewith, claims 36 and 37 have been canceled without prejudice. Upon entry of the amendments submitted herewith, claims 1-14, 21, and 24-26 remain pending in the application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination, is presented in the Listing of Claims, beginning on page 2 of this communication, with an appropriate status identifier for each claim.

Claim Rejections under 35 U.S.C. § 112 (1st Paragraph)

The rejection of claims 1, 4-14, 21 and 24-26 under 35 U.S.C. 112, first paragraph, is respectfully traversed. Specifically, Applicants respectfully disagree with the Examiner's assertion that the disclosed invention allegedly does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with these claims. (Office Action, page 3, lines 2-4).

It is respectfully submitted that the specification provides substantial information to enable any person skilled in the art to use the invention commensurate in scope with these claims, as amended herein.

Indeed, the specification is acknowledged by the Examiner as "being enabling ... to identify processes regulated by FXR activation and a method of treating hypercholesterolemia and cholestasis" (Office Action, page 2, line 21 to page 3, line 1).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Claim Rejections under 35 U.S.C. § 112 (2nd Paragraph)

The rejection of claims 1, 4-14, 21 and 24-26 under 35 U.S.C. 112, second paragraph as allegedly being indefinite, is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that the instant claims allegedly fail to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (Office Action, page 6, item 8).

Applicants' invention, as defined, for example by amended claim 1, is directed to methods for treatment of hypercholesterolemia or cholestasis comprising administering to a subject in need thereof an effective amount of at least one novel compound having a defined structure as set forth in the claims. Thus, it is respectfully submitted that the present claims particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Similarly, claims 4-14, 21 and 24-26 are directed to methods for treatment of hypercholesterolemia or cholestasis. Therefore, the rejection is not properly applied to the instant claims.

With respect to claim 12, Applicants respectfully disagree with the Examiner's assertion that there is insufficient antecedent basis in the claim for the limitation "R³ is -CH=CH-C(O)-O-tBu" (i.e., t-butoxycarbonyl-ethenyl) in the claim. Contrary to the Examiner's assertion, claim 12 properly depends on claim 11 (which requires that R³ is an alkenyl group). An "alkenyl" group, as defined at paragraph [0020] of the specification, is a hydrocarbyl group having at least 2 carbon atoms and at least one carbon-carbon double bond. This definition clearly embraces ethenyl, which is simply a 2 carbon alkenyl. The presence of t-butoxycarbonyl-substitution on the ethenyl moiety (as contemplated by claim 12) does not change the fact that R³ is still an ethenyl moiety. Therefore, claim 12 is clearly within the scope of claim 11 from which it depends.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Double Patenting

The rejection of claims 1-14, 21, 24-26, 36, and 37 on the ground of nonstatutory obviousness-type double patenting is respectfully traversed. As discussed at the personal interview, the double patenting rejection over 10/535,041 was not properly applied. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Reference for Information Disclosure Statement

As discussed at the personal interview, Applicants hereby direct the Examiner's attention to a document of potential interest, WO 04/046162 (the '162 application). Submitted herewith is Form SB/08 listing the reference of interest. The submission is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR § 1.56(b).

Indeed, as discussed at the personal interview, the claims of the '162 application are directed only to compounds. The '162 application provides only minimal disclosure regarding potential uses of such compounds, see page 5, line 2-5. At most, according to the authors of the '162 application, the '162 application "may ultimately lead to compounds having utility in the treatment of disease linked to the accumulation of toxic bile acids." (page 30, lines 2 to 3). Thus, the '162 application is not enabling of the uses contemplated herein, therefore, the '162 application is not prior art against the claims of the present invention.

CONCLUSION

In view of the above amendments and remarks, Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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